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10/706,197

11/12/2003

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12/12/2006

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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/706,197

Applicant(s)

CAMILLOCCI ET AL.

Examiner

Matthew J. Kasztejna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-40 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-5 and 7-40 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on September 25, 2006, amended claims 1, 8, 15, 22, 27, 31 and 36 are acknowledged. The current rejections of the claims under 35 USC § 103 *stand*. The following reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,380,998 to Kieffer, III et al. in view of U.S. Patent No. 5,514,074 to Yabe et al.

In regards to claims 1 and 7, Kieffer, III et al. disclose a cover having a body 41 having a recessed portion configured to releasably secure to an insertion portion of the endoscope wherein the body is configured to be disposed on the tip of the endoscope when the endoscope is not in use but are silent with respect to a disinfecting compound integral to the body. Yabe et al. teach of an analogous apparatus having an antibacterial agent is coated on the endoscope cover 2A (see Col. 4, Lines 35-40 and Col. 12, Lines 1-6). It would have been obvious to one skilled in the art at the time the invention was made to coat the cover of Kieffer, III et al. with an antibacterial agent to help prevent the growth of unwanted bacteria as taught by Yabe et al.

In regards to claim 2, Kieffer, III et al. disclose a cover, wherein the recessed portion presents a tapered profile with respect to a longitudinal axis thereof.

In regards to claim 3, Kieffer, III et al. disclose a cover, wherein the body comprises an open cell foam as it is disclosed a relatively soft material or the like is used (see Col. 3, Lines 20-45).

In regards to claim 4, Kieffer, III et al. disclose a cover, wherein the body further comprises a channel coupled to the recessed portion such that the channel and recessed portion extend through the body (see Fig. 2).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,380,998 to Kieffer, III et al. in view of U.S. Patent No. 5,514,074 to Yabe et al. in view of U.S. Patent No. 5,458,133 to Yabe et al.

In regards to claim 5, Kieffer, III et al. and Yabe et al. '074 disclose a cover having a body 41 having a recessed portion configured to releasably secure to an insertion portion of the endoscope and a disinfecting compound disposed thereon but are silent with respect to the body including an indicium configured to indicate a contamination condition. Yates et al. '133 teach of an analogous cover for an endoscope wherein an indication device for indicating whether or not an apparatus should handle a clean area in a sterile state or other area is provided on each of the components (see Col. 4, Lines 36-67). Furthermore, Yates et al. '133 teach of using the indicia to help an operator recognize whether he is working with a sterile apparatus or a contaminated apparatus. The indication means for indicating whether an area is a clean or a general area of the cover type endoscope apparatus is not limited to being a

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blue or yellow tape. Rather, in the indication means, colors to be displayed and display areas may be appropriately combined. Also, the indication means is not limited to being a color display, but symbols or characters may be used, or a combination of symbols and characters may be used. It would have been obvious to one skilled in the art at the time the invention was made to apply an indicium to the appropriate covers of Kieffer, III et al. and Yabe et al. '074 in order to allow easy recognition of the contamination status of the apparatus as taught by Yabe et al. '133. The apparatus of Kieffer, III et al. and Yabe et al. is considered to be inherently capable of performing the recited method claims.

Claims 8-13, 15-29, 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,380,998 to Kieffer, III et al. in view of U.S. Patent No. 5,458,133 to Yabe et al.

In regards to claims ~~8~~, 8-13, 15-18, 22-29, 31-36, Kieffer, III et al. disclose a cover having a body 41 having a recessed portion configured to releasably secure to an insertion portion of the endoscope and wherein the body is configured to be disposed on the tip of the endoscope when the endoscope is not in use but are silent with respect to the body including an indicium configured to indicate a contamination condition. Yates et al. teach of an analogous cover for an endoscope wherein an indication device for indicating whether or not an apparatus should handle a clean area in a sterile state or other area is provided on each of the components (see Col. 4, Lines 36-67). Furthermore, Yates et al. teach of using the indicia to help an operator recognize whether he is working with a sterile apparatus or a contaminated apparatus. The

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indication means for indicating whether an area is a clean or a general area of the cover type endoscope apparatus is not limited to being a blue or yellow tape. Rather, in the indication means, colors to be displayed and display areas may be appropriately combined. Also, the indication means is not limited to being a color display, but symbols or characters may be used, or a combination of symbols and characters may be used. It would have been obvious to one skilled in the art at the time the invention was made to apply an indicium to the appropriate covers of Kieffer, III et al. in order to allow easy recognition of the contamination status of the apparatus as taught by Yabe et al. The apparatus of Kieffer, III et al. and Yabe et al. is considered to be inherently capable of performing the recited method claims.

In regards to claims 19-21 and 37-40, Kieffer, III et al. disclose a cover wherein the first and second cover members comprise an impact absorbing material and may comprise an open cell foam or plastic material (see Col. 3, Lines 20-68).

Claims 14 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,380,998 to Kieffer, III et al. in view of U.S. Patent No. 5,458,133 to Yabe et al. in further view of U.S. Patent Application Publication No. 2002/0013510 to Moriyama.

In regards to claims 14 and 30, Kieffer, III et al. and Yabe et al. disclose a cover having a body 41 having a recessed portion configured to releasably secure to an insertion portion of the endoscope but are silent with respect to the body including an indicium having a raised surface with respect to the body. Moriyama teach of an

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analogous apparatus wherein an identification part is used to determine if an instrument is suitable for sterilization. Furthermore, Moriyama teach the indicium capable of being identified by seeing or touching from any direction. It would have been obvious to one skilled in the art at the time the invention was made to include a raised surface as the ~~indium~~ ^{indiciu}m in the apparatus of Kieffer, III et al. and Yabe et al. to provide the operator tactile feedback as taught by Moriyama.

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Response to Arguments

Applicant's arguments filed September 25, 2006 have been fully considered but they are not persuasive.

In response to applicant's argument that Kieffer and Yabe et al. do not disclose a cover disposed on an otoscope only when the otoscope is not in use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As broadly as claimed, Kieffer clearly shows a cover 41 (the removable speculum) for use with an endoscope 20 (see Fig. 2). The cover of Kieffer clearly functions to protect the endoscope both while it is not in use as well as when it is in use.

In response to applicant's argument that Kieffer is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention.

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See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Kieffer teaches of a cover 41 used with an otoscope 20, which is identical to the applicant's endeavor, being in a field of medicine related to internal anatomical cavities, some of which may include internal organs and tissues. Furthermore, applicant states that an otoscope is not by definition an endoscope. Examiner disagrees. As stated by the applicant (see page 12 of Remarks), the definition of an endoscope is "an instrument for visualizing the interior of a hollow organ (as the rectum or urethra)". The rectum or urethra are merely examples of hollow organs and are not limiting as to what an endoscope may be used to examine. An otoscope is an instrument for examining the *interior* of the ear (i.e. the ear canal), especially the eardrum, consisting essentially of a magnifying lens and a light. Thus, an otoscope is in fact an endoscope by definition and is analogous art. As broadly as claimed, the device of Kieffer meets the limitations of the rejected claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

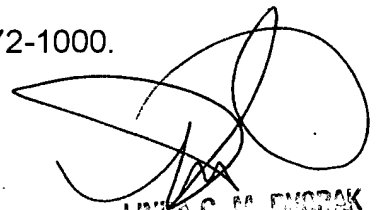
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJK *mjk*

12/4/06


LINDA C. M. DVORAK
SUPERVISOR, PATENT EXAMINER
12/4/06